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Final Report  
*Biotechnology*



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## BIOTECHNOLOGY 2009

**ABSTRACT:** Under the rubric of biotechnology lies a complex, multi-disciplinary technological effort utilizing living organisms or biological substances to produce value-added products or processes. From the life sciences to many other scientific and engineering fields, biotechnology has grown into “green” agricultural, “red” biomedical, and “white” industrial and environmental applications, leveraging the discovery of DNA molecular structure to create the modern biotechnology industry. The United States enjoys a distinct competitive advantage in both biotechnology research and development and market share. To maintain that position, national policies should facilitate research, foster technological innovation, stimulate education, and promote the economic underpinnings of this industry.

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## INTRODUCTION

Genomics. Personalized medicine. Genetically modified corn and soy for food, feed, and biofuels. Pandemic therapies. Transgenic animals and plants producing pharmaceuticals. Bio-templated electronic materials. Transcending multiple disciplines to include healthcare, manufacturing, agriculture, energy, life sciences, pharmaceuticals, chemistry, and food production, biotechnology is defined by the United Nations Convention on Biological Diversity (1992) as: "Any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use."<sup>1</sup> It also includes myriad processes, applications, and biological agents utilized during that manipulation. Biotechnology spans the boundaries of several scientific fields, involves multi-disciplinary research, affects many elements of society, and creates new capabilities in many domains.

Modern biotechnology emerged with the manipulation of genetic materials within the past sixty years, leveraging scientific breakthroughs from the discovery of DNA's double helix structure and the genetic code that allows living beings to recreate their cells.<sup>2</sup> Well-understood applications for biotech exist in the fields of medicine, agriculture, and food. Newer applications include stem cell engineering for therapeutics, biological information processing, and biological engineering. The newest applications include transgenic animals and bioengineered electronics, such as bioengineered batteries and transparent computer displays; bioremediation; biofuels; and biomimetic systems such as novel lightweight protective armor modeled on seashells. Universities established departments of biological engineering, to bring the multiple disciplines of engineering to biology and biological principles. Frontiers of biological computing and synthetic biology, both in formal institutions and by hobbyists ("DIY Biology"), emerge at a rapid pace. This survey will identify emerging applications for biotechnologies and bioengineering, and consider opportunities and challenges in the current economic and national security environment.

This industry study culminates a semester-long effort by a broad cross-section of students and faculty representing the defense establishment and industry partners. The investigative methodology employed involved guest expert lectures, travel to domestic and international biotechnology centers, and exhaustive individual study. Topics addressed include national security implications; biotechnology applications by category of use; economic considerations; political, social and ethical considerations; and the future of the industry. Most importantly, this paper identifies areas of opportunity and risk in biotechnology for America's future.

### *A Brief History*

By no means new, biotechnology traces its roots to zymotechnology (fermentation), practiced by the Sumerians and Babylonians as early as 6,000 B.C.<sup>3</sup> This core technology expanded to other applications, including using yeast to make bread, bacteria to derive yogurt, and molds to make cheeses.<sup>4</sup> Early biotechnology endeavors included selective breeding of animals and plant crops; the latter best demonstrated by Gregor Mendel's manipulation of pea plants, opening the way for the study of genetics.

Modern biotechnology traces its roots to the introduction of the term "biotechnology" in 1919 by Karl Ereky, a Hungarian engineer. Ereky coined the term to describe the use of living organisms to aid in the transformation of raw materials into useful products.<sup>5</sup> During this period, industrial applications of biotechnology such as acetone production expanded. The mid to late 1900s yielded the discovery of the DNA double helix, the ability to copy DNA using polymerase chain reactions (PCR), and the emergence of the first biotechnology firm, Genentech.<sup>6</sup> Since then, biotechnology as an industry has flourished and diversified. The report will follow a common system, categorizing biotechnology by application: "green" for agriculture, "red" for biomedical, and "white" for industrial/ environmental applications.

### *The Industry*

Categorizing biotechnology in the sector and industry model mixes large multi-national firms, entrepreneurial firms, public and private research entities, and academia into one large pool, which is neither accurate nor particularly useful when comparing national capacities and capabilities. Even the North American Industry Classification System (NAICS) data is somewhat deficient in this regard, as the designated biotechnology code (541711) primarily focuses on the biomedical applications of biotechnology, without capturing the suffusion of biotechnology into other NAICS categories such as pharmaceutical and general science, agriculture, industrial applications of biotechnology, and other emerging applications. Despite these limitations, Table 1 attempts to define the scope of biotechnology as a global industry.

Public Company Data	Global	US	Europe	Canada	Asia-Pacific
Revenues (US \$ Millions)	\$84,782 M	\$65,175 M (77%)	\$12,945 M	\$2,692 M	\$3,970 M
Research & Development	\$31,806 M	\$25,836 M (81%)	\$4,567 M	\$915 M	\$488 M
Net Loss	\$2,694 M	\$277 M	\$1,689 M	\$722 M	\$6 M
Number of Employees	204,930	134,600	47,720	7,330	15,280
Public Companies	798	386	181	82	149
Public and Private Companies	4,414	1,502	1,744	404	764

Table 1. Global Biotechnology 2007<sup>7</sup>

Given this data, certain trends such as U.S. predominance and the substantial requirement for research and development funding become apparent. What is less evident from the tabular data is the risk inherent in this industry. Financial losses can be substantial for these high risk/high-potential payoff endeavors, and can lead innovations to be deferred or lost. Time horizons are long from concept inception to marketable product. Technology transfer of scientific invention to market-adopted innovation presents non-trivial challenges, in both scientific and business aspects. For biomedical and agriculture applications, a complex and intricate set of regulatory paths must be navigated for product approval. Firms have a relatively short patent life cycle in which to recoup expenditures. Large capital resources are necessary to fund ongoing research and operations. In a globally competitive and stressed economic climate, all these factors challenge the vitality and profitability of the industry.

### ***Economic Factors of the Industry: Green, Red and White***

Industrial applications of biotechnology face different economic pressures, depending on application: green, red, and white. The challenges of firms in the slowing economy combine with expansion of applications. For “**green**” *agricultural applications*, the latest generations of bioengineered seeds and plant products for agricultural use show resilience in the face of the worldwide economic slowdown. Recent regulatory approvals of the use of transgenic animals to produce bioengineered human therapeutic treatments expand the agricultural market to cross into new biomedical applications. Bioengineered traits allow for higher productivity, more nutritional benefit, or customized characteristics. The “Green Revolution” of the 1960s continues with current bioengineered plants, bred to be resistant to pests or fungi and requiring less fertilizer and less water, which can lead to widespread environmental and economic benefits. Political challenges and social acceptance of biotechnology, particularly in the European Union (EU), slow the spread of these capabilities into new markets.

Unlike classic agriculture applications of improved seeds and plant components, “**red**” *human biomedical applications* confront current medical funding constraints and face slowdowns in future investments, as governments and insurers pursue economic efficiencies in high-end medical care. Even top-level firms such as Genzyme experienced reduced growth in revenues, both from the broad-based economic slowdown and from structural change as the biomedical intervention market matures from *life-*

saving, with high profit margins, to quality-of-life improvement, with lower profit margins. Expenses from long lead time clinical trials and Food & Drug Administration (FDA) approval process require biomedical firms to recoup their research and development (R&D) investments within seven years of patenting a new biologic or biomedical agent. This structure contributes to high medical costs for thousands of Americans. However, when biomedical agents are successful, as is hoped for human embryonic stem cell (hESC) therapies for spinal injury, the cost of a biologic agent could save hundreds of thousands of dollars while extending the life of each seriously ill person treated. The rapid development of vaccines to counter pandemics is another economically challenged but value-added application of biotechnology. The economic challenge results from surges to rush procurements to meet specific biothreats followed by periods of non-procurement. Tissue engineering to fill gaps caused by trauma offers great promise, particularly for battlefield medicine, but faces similar surge-and-withdrawal patterns of procurement.

***“White” industrial and environmental applications*** of biotechnology focus on the non-agricultural and non-biomedical. Biofuels offer alternatives to petroleum-based fuels. The US market for ethanol brought biofuel mixtures to reduce dependence on foreign oil. At the same time, current corn-based biofuels compete with food applications, which led to protests around the world. Future approaches to biofuels focus on non-food feedstocks, including cellulose and algae. Bioremediation using algae and other biological materials reduces the hazardous waste left in soil, to reduce leaching into ground water. New businesses based on biofuels and bioremediation continue to penetrate the market. The new administration’s economic stimulus efforts encourage biofuels and support bioremediation. Other emerging growth areas include bioengineered materials. Small entrepreneurial firms use bioengineered structures as the basis for “green chemistry,” using bio-mimetic approaches to create electronic structures on M13 virus scaffolds. The US Army funded development of lightweight battery components using these bioengineered materials, and expects to leverage bioengineered materials for lightweight and flexible computer displays. Timely partnering with a commercial battery maker and major power tool vendor accelerated the transition of these bioengineered batteries to market, driving down costs and speeding up the improvement curve. The combination of commercial market with government-funded R&D and systems procurement make biotechnology a key enabler in these domains.

The economic scope of all three types of biotechnology application can be challenging to capture. Standard NAICS codes used to categorize less complex, less cross-cutting industries do not cover all aspects of biotechnology. Some of the biomedical applications fall under health care, some under pharmaceuticals. For agriculture, genetically modified seed and compatible herbicides are combined with conventional agriculture products. The NASDAQ lists a biotechnology index for the American stock market that also focuses primarily on red and white biotechnology applications. Emergent approaches such as bioengineered gene-templated electronic materials for computer displays create novel capabilities not found in nature. However, the economic span of biotechnology reflects in a variety of metrics.

The chart below shows the PricewaterhouseCoopers/National Venture Capital Association’s MoneyTree report, reflecting the American venture capital investments in biotechnology. For US biotechnology venture investments in the 15 years from 1995 to 2009 (current year annualized), more than \$46 billion in venture capital was invested in over 5000 deals in “developers of technology promoting drug development, disease treatment, and a deeper understanding of living organisms, including human, animal, and industrial biotechnology products and services; and biosensors, biotechnology equipment, and pharmaceuticals.”<sup>8</sup> Even with the current economic slowdown and collapse of venture capital, biotechnology remains in the top three categories of equity investment and represents a significant focus for private equity investors. The venture capitalists often leverage US public investment in biotechnologies, including National Institutes of Health (NIH), Center for Disease Control (CDC), Department of Agriculture (USDA), and Department of Defense (DoD). DoD-funded biotechnology activities include Walter Reed Army Institute for Research, US Army Medical Research

Institute for Infectious Diseases, Institute for Soldier Nanotechnologies, and Institute for Collaborative Biotechnologies. Public-private partnerships strengthen this emerging industry across all applications.

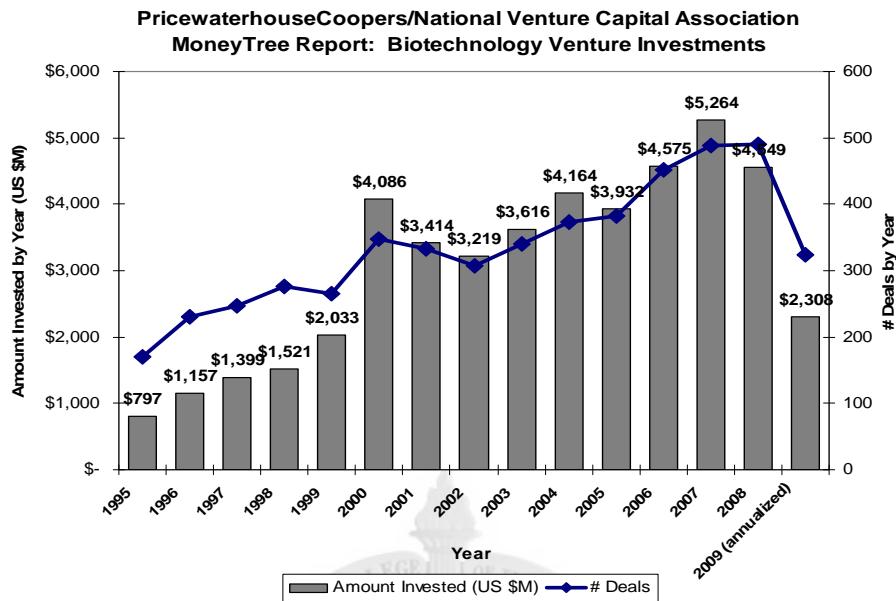


Figure 1. Biotechnology Venture Investments (as of 18 April 2009).

Scientific and technological investments, on a national scale, yield unique ancillary benefits. First, these investments drive innovation and scientific breakthroughs, which spur additional research, additional discoveries, and spinout business development. For example, the human genome project<sup>9</sup> paved the way for more expansive DNA research. Second, these activities attract human capital, adding talent to the work force. Third, progress in these areas establishes core competencies, which lead to standards, official and unofficial, for the community. US patents and Food and Drug Administration (FDA) approval certifications are the “gold standard” for biotechnology endeavors, regardless of national origin. Finally, biotechnology investment provides a conduit for global interaction and collaboration, linking the international community. Global efforts to apply biotechnology in support of pandemic influenza and collaboration towards HIV/AIDS and malaria research and treatment are two examples.

## National Security Implications

The nature of the relationship of US national security to the biotechnology industry depends on the national security context one presupposes. At one pole, the approach taken by the Bush administration responded to the dire national security threats of the time of terrorism and focused on the need to “rally the great promise of American science and innovation to confront the greatest danger of our time.”<sup>10</sup> The current economic and environmental challenges bring the Obama administration to focus more on the economic growth potential of biotechnology across all domains. In this regard, biotechnology provides an engine for innovation and economic growth, allowing for new high-skill job creation and new businesses that can propel the American economy and has the potential to bestow a more stable national and global environment.

The biotechnology industry has done much to improve the quality of human lives. However, this combination of science and technology and all the potential for good that it brings to humanity also brings the capability to do significant harm. This uncertainty of how biotechnology will be applied and the capability to do significant harm invokes fear and potentially terror.

### ***Bioterrorism – National Security Concerns***

In Fall 2001, anthrax-laced letters were mailed to news media offices on the east coast of the United States and to US Senate offices. With this act of bioterrorism, twenty-two individuals were exposed to anthrax spores; five people died; operation of the federal government and postal system were disrupted for months; and decontamination of the Hart Senate Office Building and other offices on Capitol Hill cost over \$42 million. Decontaminating the Brentwood postal facilities in Washington, DC and postal facilities in Hamilton Township, NJ was estimated to cost another \$100 million.<sup>11</sup>

Much has been done to identify vulnerabilities and secure the US homeland following the terrorist attacks of September 11, 2001 and anthrax attacks of 2001. Vulnerability to bioterrorism in the US and the planned response has focused primarily on terrorist use of biological agents to attack the human population. While the use of agents like anthrax, smallpox, plague, or tularemia remains a possibility and significant threat, there is also a secondary threat of a deliberate introduction of biological agents causing animal or plant diseases into the US agricultural and food supply.

Agricultural bioterrorism is a ***low cost, high impact threat*** to America. Agricultural bioterrorism is commonly described as the deliberate introduction of an animal or plant disease with the goal of generating widespread fear, economic disruption, uncertainty in the safety of the food supply, and/or loss of confidence and destabilization in government. Likely vectors of agricultural bioterrorism include viruses, bacteria, or fungi.

As a world leader in food production, the agriculture industry accounts for one-sixth of the US Gross Domestic Product (GDP). The US produces and exports a large share of the world's grain supply. US agriculture industry and food supply sector directly employs over 16% of the nation's workforce including farmers and suppliers, food processors, shippers, grocers, and restaurant owners.<sup>12</sup>

Animal sickness and disease are always of concern to ranchers, farmers, and breeders. However, intentional introduction of a foreign animal disease presents the likeliest scenario for an agriculture bioterrorism attack. The disease potential, ease of dissemination, and close concentration of livestock increase the likelihood of spread of disease and contribute to the devastation. Any delay in recognizing symptoms of animal or crop disease might result in a significant outbreak, affecting speed and efficacy of response. The USDA publishes a prioritized list of animal diseases that could be used as agricultural bioterrorism agents against US livestock, and include foot and mouth disease, avian influenza, Newcastle disease, and swine fever.<sup>13</sup> Similarly, the USDA tracks food crop pathogens, particularly fungi, bacteria, and viruses, that could be exploited for agricultural bioterrorism targeting food crops.

Potential bioterrorism targets can be found anywhere along the food supply chain from farms where products are grown, to the transportation network used to move products from farm to market, to warehouse or processing facilities where products are prepared for sale, or ultimately at wholesale or retail facilities where products are sold to consumers. As demonstrated in recent food safety scares, susceptibility and vulnerability to agricultural bioterrorism can be difficult to address systematically because of geographic dispersion, industry concentrations, ease of bioagent deployment, and difficulty in separating a deliberate bioterrorism attack from the inherent biology of growing plants and animals.

Economic losses from an agriculture bioterrorism attack are likely to be large and widespread. Individuals, businesses, and governments all may experience direct and indirect costs resulting from deliberate introduction of an animal or plant disease into the food supply. As demonstrated during outbreaks of hoof and mouth disease, direct costs include diagnostic testing, pesticides, herbicides, veterinary services and drugs, and the cost of destroying diseased livestock or contaminated products. Indirect costs and losses result from government restrictions on products, nation-wide recalls, or destruction of livestock or crops to prevent the spread of disease. Even the suspected presence of pests or

diseases can stop exports of an agricultural commodity, as experienced for beef during the “mad cow” scare. Economic effects ripple broadly due to decreased sales by businesses dependent on agriculture, such as farm suppliers, food manufacturing, transportation, retail grocers, and food service providers.

### ***Protecting Agriculture and Public Health***

The agriculture industry is a significant and important component of the United States and world economy. Several select agents and toxin are of greatest concern and likeliest threats against livestock and crops in the United States. The economic impact of a bioterrorist attack on agriculture could be significant, so federal, state, and local authorities employ resources to monitor and detect disease outbreak. These resources allow authorities to diagnose and respond quickly, safeguard health, save lives, and mitigate the intended affects of a bioterrorism attack on agriculture and the US food supply system.

### ***Bio-defense and Pandemic Preparedness***

Bio-defense did not commence on July 21, 2004 with the passage of the BioShield Act. History offers many examples of biological warfare and defensive countermeasures.<sup>14</sup> However, BioShield did focus R&D and procurement on medical countermeasures against biological, chemical, radiological, and nuclear (CBRN) agents.<sup>15</sup> These funds integrate medical countermeasure acquisitions with emergency response plans, for a comprehensive bio-defense strategy. The current administration’s homeland security initiatives support American bio-security by calling for prevention of bio-terror attacks, building capacity to mitigate bio-terror attack effects, accelerating the development of new medicines and vaccines, and leading an international effort to diminish the impacts of major infectious disease epidemics.<sup>16</sup> The current response to the new H1N1 swine flu outbreak benefits from these investments.

*“The global community has suffered recently from newly emerged infectious diseases, including HIV/AIDS and severe acute respiratory syndrome (SARS), and from reemerging diseases once thought to be in decline. The world now faces the threat of a human influenza pandemic arising from the recently emerged avian influenza H5N1 virus. It has been increasingly recognized that infectious disease can have significant effects on US and world security.”<sup>17</sup>*

This quote highlights the fact that infectious disease poses a true threat to both US and global security, and requires sustained vigilance by US and world policy makers. Historically, infectious diseases have threatened the security of armies and civilizations worldwide, whether spread purposefully via bioweapons or naturally through pandemics. Globalization allows a faster spread of infectious disease worldwide, enhancing global risk, as shown in the current swine flu outbreak.

Since the first case of influenza A(H1N1) infection in Mexico was identified in April 2009, as of May 2009 the worldwide total was 10,243 cases with 80 deaths in 41 countries.<sup>18</sup> To minimize the worldwide security threat posed by this outbreak and future pandemics, US policy makers must institute domestic measures and work closely with the World Health Organization and international partners to mitigate global infectious disease threats. Global collaboration is essential, specifically in the areas of disease detection, prevention and treatment. Such support during this swine flu outbreak has already resulted in identification of this deadly virus and shapes the development of new vaccines.

Under the Department of Health and Human Services, the Centers for Disease Control and Prevention (CDC) and CDC’s Coordinating Office of Terrorism Preparedness and Emergency Response (COTPER) play a major role in defending against bioterror attacks. COTPER’s mission is to safeguard health and save lives by providing a platform for public health emergency response.<sup>19</sup> State and local governments have primary responsibility for incident response with federal assistance provided in

accordance with the National Response Framework (NRF) and Stafford Disaster Relief and Emergency Assistance Act. CDC maintains disease surveillance and outbreak detection systems:

- PulseNet – outbreak detection system for food-borne, disease-causing bacteria to identify clusters of cases that might be related. Once a contaminated food source has been identified, public health action to control the outbreak can be taken.<sup>20</sup>
- BioSense – national real-time bio-surveillance and health situational awareness from access to current human health data from health organizations across the country. BioSense supports public health decision-making and response coordination for disease, bioterrorism, or catastrophe.<sup>21</sup>
- Laboratory Response Network (LRN) – network of 150 laboratories (state and local public health, veterinary, military, international) that are equipped to respond quickly to acts of chemical or biological terrorism, emerging infectious diseases and pandemic, and other public health threats.<sup>22</sup>

### **“Green” Applications of Biotech for Food, Feed, and Fiber**

An escalating global population presents many challenges to include a potential shortage of food, limited energy supply, and increased environmental pollution. The advances in biotechnology provide a means to mitigate these issues by increasing yield in food production, providing alternative energy sources, reducing the hazardous materials needed for manufacturing, and enabling a cost-effective means to clean up environmental waste. While biotechnology offers significant potential to improve human and environmental health, first generation products seek profitability to demonstrate benefits to consumers. Some applications are not embraced by the public due to ethical and social-economic issues. However, success in development of the first generation of biotechnology products for food and the environment may ultimately lead to additional investment, global acceptance, and an overall benefit to society.

#### ***Food Production & Food Security***

In December 2008, United Nations representatives stated that for the first time in history, one billion people would go hungry this year.<sup>23</sup> While some populations enjoy food surplus, other populations suffer from shortages and from inadequate distribution of food systems linking production areas to those in need. Shortages of food will increase as a concern, as the global population is predicted to exceed nine billion people by the year 2050.<sup>24</sup> This increase in the world's population will surpass the world's food production capacities unless dramatic improvements in agricultural technologies are discovered and implemented. Furthermore, biofuel feedstock requirements compete with food to exacerbate shortages.

Increasing the allocation of farm land and distributing more fresh water for crop irrigation to increase food production is not a sustainable option to meet future demands. However, improving crop production through the use of genetics offers a sustainable alternative. Companies such as Monsanto conduct plant genetic modifications to enhance plants' resistance to insects and weed control chemicals, and to improve crop yields by improving drought tolerance and fertilizer utilization.<sup>25</sup> The resulting plants are referred to as “genetically modified” (GM). Genetic research also pursues improved plant nutrition, such as Florida researchers’ GM tomatoes to increase folate availability for human health.<sup>26</sup>

For its many benefits, GM crops face skepticism in parts of the world, particularly in Europe where a common perception is that GM foods are unsafe to eat and may harm the environment. Europe has adopted a “precautionary principle” for accepting GM products, which led to a restrictive trade policy, whereas the US opened its market to biotechnology applications. This polarization of regulatory policy is stifling trade of GM crops on the international market.<sup>27</sup> These concerns can be overcome.

Genetic modification of agriculture follows millenia of selective breeding of animals and plants, and has been practiced safely for over a decade; there are now over two billion acres of land worldwide in production of GM crops.<sup>28</sup> US policy makers embraced agricultural biotechnology while adopting a scientific approach to ensure the products are safe for animal and human health and safe for the environment. However, trade barriers must be overcome to enable GM foods to enter the European and other international markets. As seen during the industry travels to Poland and the Czech Republic, substantial amounts of crop damage due to pests such as the European corn borer increase the eagerness of European farmers to use genetically engineered crops designed to thrive despite the pests.

Europe's moratorium on approval of biotech crops into the European market was to appease public opinion that the crops were not safe. This not only affected new crops entering the market, but also some European countries unilaterally banned the import of GM products that had been approved by the EU. The WTO ruled that the EU broke international trade rules by blocking the import of genetically modified food products by delaying a European Sanitary and Phytosanitary (SPS) procedure to assess the risks to humans, animals, and plant health. The WTO ruled the moratorium did not constitute a technical barrier to trade, and the ruling did not require Europe to change its approval process. In the end, it did little to alter the negative public perception of GM foods in European countries.<sup>29</sup> The result is that the US still faces considerable trade barriers for GM foods to enter European and international markets.

Benefits from GM agriculture have only begun to be realized. In the future, biotechnology will improve human health by using GM plants to grow vaccines and medicines cheaply and in a variety of locations. GM tobacco plants growing a potent anti-inflammatory protein called interleukin-10 (IL-10) could help patients with insulin-dependent diabetes and other autoimmune diseases.<sup>30</sup> Plant scientists now experiment with switchgrass as a platform to grow bioplastics which can biodegrade at the end of their useful life. Benefits will also be realized by enhancing plant resilience to temperature extremes and drought and seawater tolerance. Bioengineered plants can provide food, feed and fiber for the world.

### **“Red” Biomedical Applications: Helping Nature Heal Better**

*“I firmly believe that we stand on the cusp of an unprecedented period of discovery and invention in the life sciences.... [T]he gap between medicine as an art and a true science may finally be closing. ... The canvass of human health looks vastly better today than it did...with many more of the details filled in by artists of personalized medicine.”<sup>31</sup>*

– Sydney Taurel

Thus far, biotechnology has given incredible discoveries and significant medical advancements. The mapping of the human genome gave scientists a view of the potential of human medicine and gave cause for celebration by those for whom genetics holds the key for quality and quantity of life. While significant, that advancement was just one step along humankind's long and challenging journey in biotechnology. The use of genetics in medicine is in early stages, as companies offer diagnostic assays of genes that appear linked to various types of cancer.<sup>32</sup> Learning more about the human body gives hope that biotechnology will indeed accelerate availability of better health for less money for more people. Given the broad nature of this set of biotechnology applications, we will consider three issues: personalized medicine, genetic testing and counseling, and stem cells. Questions such as who decides what information to provide patients and health decision-making bring ethical considerations, which will be discussed in a later section.

#### ***Personalized Medicine***

Many consider the ultimate application of biotechnology be personalized medicine, which seeks to tailor therapies to a person's own genetic profile. Genomics and genetic diagnostics will shape disease prevention, diagnosis, and treatment.<sup>33</sup> Personalized medicine applies the new genetic analysis tools

directly to the diagnosis, understanding and treatment of disease. By understanding a person's individual genetic blueprint, scientists hope to move medicine from reacting according to statistical population norms to personalized preventive behavior and treatment. Living healthily benefits individuals and societies much more than trying to catch disease and pursue lengthy and costly treatment protocols.

Personalized medicine presents broad opportunities. Understanding the patient from the cellular level can help identify treatment strategies and drug therapies to take advantage of the genetic strengths and avoid genetic weaknesses, allowing people greater control over their own healthcare. Decisions based on genetic information should reduce side effects and improve health by prescribing the right medicine, in the right dose, at the right time. Combined with bioengineered transdermal and implanted drug delivery systems, tailored biotherapies could substantially reduce harmful side effects, while responding to the specific chemical configuration of the patient each moment. The transformative effect of this approach to medical care on our costliest diseases – heart disease, diabetes, cancer, asthma or respiratory disease – could substantially reduce long-term healthcare costs. Though use of genomics is expanding, many questions remain, including funding, regulation, cost, patient privacy and informed consent. These questions will have a significant impact on the future of biotechnology and medicine.

### ***Genetic Counseling and Genetic Testing***

One ethical dilemma arising from genomics is genetic counseling (GC) and genetic testing (GT). GC seeks to inform patients and their relatives who are at risk of an inheritable disorder are advised of “the consequences and nature of the disorder, the probability of developing or transmitting it, and the options open to them in management and family planning in order to prevent, avoid or ameliorate it.”<sup>34</sup> Ideally, GC involves qualified genetic counselors to serve as both genetic advisors and patient advocates. Responsible GC requires that the genetic counselor explain in detail the benefits, risks, legal rights and limitations related to GT, so patients can make appropriate GT decisions.

GT is complex, both medically and socially. Medically, many diseases relate to clusters of genes that act in combination with environment, health history, and lifestyle. The same external disease, such as breast cancer or leukemia, can result from several genetic configurations. Ambiguous results, false positives, and false negative results compound the complexity of the GT interpretation. Genetic counselors must help patients understand the limitations of GT, particularly for deadly disorders, such as Huntington's Disease (HD). Although knowing one has HD gene mutations helps some people with reproductive and career planning, genetic counselors worry about potential psychological damage, stigmatization and discriminatory harms from testing.<sup>35</sup> Even if responsible GC and appropriate GT are practiced, dilemmas abound. Is it better to know that one may die in years from a disease? What are the obligations between family members who are tested and those who chose not to know GT results? While these ethical dilemmas are not new, recent advances in GT confront more people with the challenges.

### ***Direct-to-Consumer Genetic Testing (DTC)***

In contrast to GC lies the emerging field of DTC genetic testing. In traditional medicine, the provider, usually a physician, evaluates a patient and orders specific genetic tests to prove or disprove a diagnosis. DTC GT differs from traditional GT since patients order the tests on their own, based on a number of personal motivations. No GC, physician, or other licensed health care provider determines the appropriateness of GT or interprets results for the patient. Because of this, DTC GT offers distinct consumer benefits. First, consumers can directly determine their own need or desire for GT rather than going through a gatekeeper or health care provider. DTC GT offers privacy: no results need be included in the consumer's individual medical record. Thirdly, DTC GT provides consumers independent information to choose potential courses of action based on their own knowledge and values, not those of a provider. Finally, DTC testing provides convenience. Consumers can find answers to questions of their

disease susceptibility related to genetic factors from home without the costs and hassle of scheduling multiple provider appointments, filling out insurance forms, or additional non-value added costs.

Traditional medicine views DTC GT as inappropriate because the consumer will likely not have the knowledge necessary to understand completely the test results. In some ways, traditionalists are correct. Consumers may think they are purchasing binary information from DTC companies—either the gene is present or not, and the gene does or does not cause the disease. In actuality, the data they are purchasing is much more complex. According to recent articles, more than one thousand genetic tests are available today. However, given the early stages of the endeavor, many provide little evidence of clinically proven value. Moreover, the regulatory infrastructure to demonstrate the utility and validity of these tests is largely nonfunctional or nonexistent.<sup>36</sup> From this point of view, allowing patients unrestricted access to DTC GT is problematic because patients may not have scientifically valid reasons for the testing.

The argument for restricting DTC GT is based on an assumption that specialized scientific knowledge is the only framework in which GT should be obtained and interpreted. In an ideal world, this might be true. However, in reality, patients have many personal reasons for wanting GT, not all of which fit clinical medicine’s indications. These personal reasons are no less valid than scientific ones. Furthermore, once a patient receives DTC GT results, healthcare providers can assist with interpretation. Thus, the professional gatekeeper protecting patients is still in place, albeit in a different form.

Policymakers should be hesitant of increasing regulatory control over the rapidly emerging field of GT. Rather, policymakers should encourage the creation of new technologies and new applications for genomics and GT. Market forces and engaged patient advocacy groups can steer the industry into the creation of value for patients before government control emerges. Personal and societal ethics will help shape the industry. The ultimate winners of this approach will be patients. Allowing patients unrestricted access to genomics and GT will allow the industry to mature rapidly to its fullest potential.

### ***Stem Cell Research***

Most cells within an organism are committed to fulfilling a single function within the body. In contrast, human embryonic stem cells (hESC) are a unique and important set of cells that are not specialized. Instead, hESC retain “pluripotency,” the ability to become any of more than 200 different cell types in the human body, and play a critical role in repairing organs and tissues throughout life.<sup>37</sup> Stem cell researchers explore how cells grow and differentiate into different tissues, including nerves, organs, skin, and bone. Stem cell research first began in the early 1980’s with the first human stem cell discovery as recent as 1996. This technology is in its infancy state -- just 13 years in development – but the promise of harnessing cellular medicine is potentially limitless. Understanding these processes may shed light on non-normal development. Eventually, stem cells may correct genetic problems and repair damaged tissues, restoring normal structure and function. An extreme application of this would be to grow replacement organs or limbs, using regenerative medicine to mitigate traumatic injury or disease.

Stem cells also can offer a test bed of a person’s own cells to test pharmaceutical treatments for efficacy or toxicity. This personalized medicine approach allows doctors to select the right level and combination of therapies to treat a medical problem, while reducing damaging side effects. Whole-body treatments such as chemotherapy for cancer currently affect patients with savage side effects – reducing the amount, targeting the therapy, and providing complementary stem cell therapy to grow healthy new cells could revolutionize cancer treatment. This summer, a Cambridge, MA biotechnology firm plans to begin human clinical trials on their spine injury therapy, which incorporates biocompatible polymer with bioengineered human neural stem cells.<sup>38</sup> Bioengineered polymers plus neural stem cells could restore

neuroplasticity and spinal function, demonstrating early promise for stem cell therapies to solve major human health challenges.

Controversy around stem cell research derives not from the potential medical benefits, but from the source of the stem cells. Four broad approaches can be used to derive stem cells: (1) extracting cells from non-living embryos; or (2) non-harmful biopsy of living embryos; (3) extracting cells from artificially created non-embryonic but embryo-like cellular systems; and (4) de-differentiation of somatic cells (such as skin cells) back to pluripotency.<sup>39</sup> Some people believe that embryos are human from the moment of their creation, and thus acting upon them violates their ethics. Other people believe that human life occurs later, and thus use of embryos would be permissible.

Because of this fundamental dichotomy, researchers pursue avenues to derive viable stem cells from other sources than embryos. The search for alternative pluripotent stem cells is broadening and has already produced promising results. Induced pluripotent stem (IPS) cells appear to have the properties of embryonic stem cells and although they are unsuitable for therapeutic use, they represent one step closer towards the practical application of cellular medicine.<sup>40</sup> Another alternative that could eliminate the use of embryos is reprogramming skin cells. If effective, this technique could create a limitless source of stem cells that eliminate tissue rejection issues because they are taken from the user. New studies suggest that cells from human blood can morph into stem cells, express the same makers as embryonic stem cells and share the same capacity to differentiate into specialized cells. These cells must be characterized well before use in human beings – for example, to ensure that the cells can turn off after activation (so they do not act like cancer in their human patients).

If possible, making pluripotent stem cells from blood, the easiest tissue to obtain, may provide an easier strategy for generating patient-specific stem cells.”<sup>41</sup> All the alternatives in this cutting-edge scientific endeavor strongly support the need for more research. The Obama administration’s commitment to provide federal funding for stem cell research and for R&D more broadly provides a base upon which these biotechnologies can build.

Curing Parkinson’s disease can be a shared good, while source of stem cells generates discussion and political debate. Former President Bush authorized federal funding for stem cell research but limited funding to research conducted on stem cell lines created before 2001. President Obama recently rescinded President Bush’s executive order and is expected to expand research funding. NIH is expected to publish new guidance in July 2009 and may authorize the research use of more than 500,000 frozen embryos created for in vitro fertilization (IVF) that are routinely destroyed annually.<sup>42</sup> It is unclear how dramatic Obama’s approach will be, but according to recent public opinion, over 64%<sup>43</sup> of the nation believes the executive order is a significant move in the right direction.<sup>44</sup>

However, presidential policy is not the only legal framework. Law embodied in the Dickey Amendment that prevents the “creation of a human embryo or embryos for research purposes; or research in which a human embryo or embryos are destroyed”<sup>45</sup> will remain intact and continue to provide legal and ethical boundaries for researchers. Historically, medical discoveries have taken generations for full implementation, and narrow understanding and awareness masked what seems obvious today yesterday. Stem cell research offers promise and the hope that one day this technology will lead to avoidance and cure of illness and disease.

Clearly, biotechnology has already revolutionized the practice of medicine and will continue to do so in the future. Treatments will become individualized to each patient rather than being based on generalizations and averages, to increase the probability of success and lower the risk of complications. However, as knowledge progresses, our understanding of the relationship between humans and the genome will be challenged. The moral, ethical, legal, and regulatory issues surrounding the use of

biotechnology in medicine need to be understood and widely addressed to ensure that the biotechnology industry can deliver its fullest potential to humankind. A later section will consider these ethical issues.

## **“White” Applications of Biotechnology for Industry and Environment**

While green biotechnology’s agricultural applications emerge from millennia of human selective breeding of animals and plants, and red biomedical applications of biotechnology draw their lineage back to the healing arts, “white” biotechnology applications include new and emerging non-medical and non-agricultural approaches. Biofuels result from biotechnology to create new sources of energy, particularly from non-traditional feedstocks such as GM algae. Bioremediation using plants and enzymes cleans up hazardous waste in the environment. New and emerging applications include genetically engineering new electronic materials, based on bioengineered viruses as templates for electronics, batteries, and computer displays. This “genes-to-electronics” approach allows “green” manufacturing, reducing hazardous materials input to and resulting from electronics manufacturing.

In addition to more environmentally friendly and lower-cost approaches to manufacturing, harnessing the approaches nature uses to create elaborate and strong systems such as seashells with nanoscale features could allow production of systems that are simply not possible by standard manufacturing techniques. Bioengineering pursues these biomimetic approaches to tackle big challenges that confront DoD and our nation going forward, from portable power generation, to personal protection systems, to creating new materials and new capabilities.

### ***Biofuel***

Americans are the world’s largest user of oil and oil products and account for nearly one-fourth of the total global demand for oil.<sup>46</sup> However, the world oil supply is dwindling and new sources of energy need to be found. Fuels produced using biotechnology, such as bioethanol and biodiesel are one potential oil replacement. Although biofuels may be a candidate to replace oil as a fuel source, the challenge is to produce these fuels from sustainable plants and biomass efficiently.

Current ethanol refining in the United States uses corn as the source of glucose, which is the key starting point for developing ethyl alcohol or ethanol. This first generation process uses the fermentation of sugars or starches to produce ethanol but is dependent upon corn, a primary food crop. Cellulosic ethanol, a second-generation biofuel, will utilize waste materials and other feedstock that do not figure centrally in the food supply.<sup>47</sup> This method would enable the processing of the entire plant, producing more energy per acre – if scientists figure out how to break down cellulose efficiently. Algae, a potential third-generation biofuel, holds great promise since it generates fifteen times more oil per acre than other plants used for biofuel production.<sup>48</sup> Other third generation biofuels could be produced by genetically engineering plants to exhibit desired traits such as oil production. As the industry study viewed in Central Europe, GM rapeseed plants may lead the bioethanol field.

The federal government has provided tax incentives to develop the domestic ethanol industry and decrease our dependence on foreign oil. Domestic ethanol producers also enjoy the protection of import duties on imported ethanol such as a 2.5 percent ad valorem tax, and a secondary tariff of \$.54 per gallon.<sup>49</sup> In addition, domestic fuel distributors receive a \$.45 per gallon subsidy for ethanol. The Renewable Fuel Standard included in the Energy Independence and Security Act of 2007 calls for significant increases in ethanol production; 36 billion gallons per year by 2022.<sup>50</sup>

The 2008 National Strategy for Energy Security acknowledges the potential for next generation biofuels and recommends that the United States focus on development and commercialization of the next

generation of biofuels.<sup>51</sup> Current corn-based ethanol production certainly helps reduce our reliance on foreign oil but the future lies with cellulosic ethanol and other advanced biofuels.

### ***Bioremediation: Environmental Pollution Solution Tool***

*“Since the 1980’s managing environmental risk has been accepted as a cost of doing business. But a toxic spill, leak, or discharge may have the potential to become a staggeringly expensive, long-term problem. For many firms, that is a cost too high to bear.”<sup>52</sup>*

Waste byproducts from industrial and military facilities continue to be an environmental pollution issue. As the EPA and individual states raised standards to decrease natural resource damage, companies face high costs for environmental impact studies and remediation at their industrial facilities. Essentially, two approaches allow for contaminated soil or water bioremediation either *in situ* (on site) or *ex situ* (off site): either using microorganisms or plants to take up the toxins, or microorganisms, chemicals, or enzymes to break down the toxins. Plants that take up the toxins into their cellular structures can then be harvested, to extract the toxins for reuse or to incinerate them.<sup>53</sup> Treating pollution *in situ* takes time, but reduces the risk of transferring toxins to the atmosphere. The high cost *ex situ* contends with the problems of ground transfer of soil and a large land space required for treatment.<sup>54</sup> Biotechnology can enhance the efficacy of plants to uptake toxins, or to convert toxins into biofuels feedstocks.

In 2007, the US Environmental Protection Agency (EPA) stated that over 294,000 sites would require remediation in the next 30 years. Due to industrial chemical runoff causing contaminated soils and water tables nationwide, the EPA estimated remediation costs of \$209 billion.<sup>55</sup> Within DoD alone, \$20 billion went during the past decade to remediate groundwater contamination on 6,000 bases and facilities. Previously DoD relied on *ex situ* “pump-and-treat” technology, but recently, DoD moved to alternative and less costly *in situ* methods that exercise a variety of bioremediation methods.<sup>56</sup> The scale of clean up requires the most economical and feasible approaches to bioremediation. Bioremediation through natural and GM organisms offers the capability to reduce environmental deterioration.<sup>57</sup>

The fear of the unknown regarding GM organisms created roadblocks. EPA, a risk adverse organization, tends to view these microorganisms as threats instead of opportunities to promote a cleaner environment. This cautious attitude holds bioremediation stagnant. A proactive approach to educating legislators and the public on safe science and research in biotechnology will accelerate its full acceptance, development, and employment. Public-private partnerships between governmental agencies, industry, and universities in R&D will greatly improve its potential and future utilization.<sup>58</sup>

Bioremediation cannot be the sole solution to our complex environmental problems, but provides essential tools to alleviate pollution. To be most effective, bioremediation must develop to reduce the time required to refurbish soil or groundwater. Proactive implementation can mitigate pollution risk. Industrial applications of the past century polluted significant amounts of land, air, and water. Biotechnology offers promise to clean the environment and produce fewer future hazardous materials.

### **Political and Social Impacts of Biotechnology**

As with any new technology, the ability of scientists and innovators to bring biotechnology to life in products and capabilities emerges faster than the society can understand. A major change in the technologies upon which we rely requires a major education effort, across all our society. As earlier technologies demonstrated, using new capabilities brings unexpected benefits and harms. Rather than defer use of any biotechnologies until scientists fully characterize them, an engaged populace must consider political and social impacts and best uses.

## ***Regulatory Activities***

With the advent of more sophisticated products, such as those resulting from the biotechnology industry, regulatory authorities like the US Food and Drug Administration (FDA), the European Food Safety Authority (EFSA), and European Medicines Agency (EMEA) are concerned about their ability to maintain consumer protection standards for the resulting products with their new complexities and uncertain risks.<sup>59</sup> The basic mission of the FDA, the EFSA, and the EMEA is basically the same: to maintain the integrity of the food and drug supplies for their respective populations. The FDA requires a demonstration of both safety and efficacy of new products and retains sole power to license new products throughout the United States, while the EFSA and EMEA primarily focus on new product safety and make recommendations to the European Commission, a political body, with regard to licensure.

US and EU regulatory systems are similar and significant progress towards harmonization has been made, with frequent sharing of data on products. However, it is unlikely that the EFSA, EMEA, and FDA will achieve full reciprocity, or recognize each other's approvals to market, due to economic and political influences. Despite ongoing harmonization, disagreements between the US and EU do occur, particularly in the areas of biotech foods. Numerous calls for reform of regulatory systems ring out from both sides of the Atlantic. FDA reform proposals range from strengthening the regulatory oversight for food, to removing responsibility for food from the FDA and assign it to USDA.<sup>60</sup> For others, the issue revolves around intellectual property protection, marketing pharmaceuticals directly to consumers, cost of drugs, or length of time required to achieve FDA approval.<sup>61</sup>

Regardless of the reformist cause du jour, the implication is that the FDA is not strategically structured and equipped to conduct timely and cost efficient reviews of increasingly complex substances needing approval. Proposals for reform of the EFSA and EMEA also reflect common themes. From a US perspective, the EU process appears unnecessarily political, inefficient, and arbitrary, but works for its environment. The regulatory environment for biotechnology in both the US and the EU is well defined, yet will most likely require modification as the complexity and quantity of both biotech foods and drugs expands in the coming years.

## ***Drug Approval***

Inventors register new inventions with the US Patent and Trademark Office (USPTO) to protect their intellectual property, allowing them to “exclude others from making, using, selling, offering to sell, or importing into the United States the patented invention.”<sup>62</sup> In the past decade, US patent applications increased greatly in quantity, scope, and multi-disciplinary complexity. The twenty-year duration of a patent does not mean the drug manufacturer has twenty years to sell their product and make their investment back. Given the time required, clinical trials to assess safety and demonstrate medical utility, and scale the product up for marketing can consume fourteen or more years from time of drug discovery to market. This leaves only six years of patent-protected time for the drug companies to recoup development costs before the drug patent expires, allowing for generics.<sup>63</sup>

This complex FDA drug patent life cycle forces biotech companies to seek new ways to offset development investment, including paying the FDA a “user fee” to focus FDA attention on speedy consideration of their product<sup>64</sup>, industrial secrecy, directed marketing to consumers (DTCA) with celebrity endorsement, and heady pricing depending on the marketing area.<sup>65</sup> Additionally, large pharmaceuticals are increasingly reformulating currently patent-protected products, restarting a new period of patent protection for reformulated products.

### ***Ethical Considerations***

The rapid pace of change in various biotechnology applications brings new focus on ethical considerations. New diagnostic tests for breast cancer based on testing seventy genes could transform breast cancer detection and treatment. However, in a society with millions of Americans who have no health care coverage, who should receive access to this costly new diagnostic? Shall consumers order and pay for this test as a luxury, or should health insurers pay? Might Americans face discrimination, if they indicate a precursor for a specific type of disease? What about diseases for which there is no treatment? Alzheimer's syndrome impacts brain function with slow decline over years; Huntington's patients can harbor the disease without symptoms for years. Would the more ethical course be to disclose potential impacts to patients, or to protect patients until either symptoms or treatment appear?

Medical treatment ethical challenges extend to pharmaceuticals produced by bioengineering. What is the ethical status of a transgenic animal that incorporates human genetic materials to produce useful pharmaceuticals, such as transgenic goats that produce human anticoagulants in their milk, or pigs that produce human insulin? Does being partly human bring animals or plants special status? Are there species barriers that should not be crossed?

The debate on human embryonic stem cell research raises ethical issues among many communities. President Obama recently reversed former President Bush's prohibition on using federal funding for research into use of human embryonic stem cells for therapeutic treatments. Advocates of the research urge its expansion. Stem cell therapies could fulfill their promise to regenerate damaged nerve tissues, to address Parkinson's and other nervous system disorders; to regenerate spinal tissue and heal spinal injuries; to regrow brain cells, to cure Alzheimer's and other degenerative brain diseases; to regenerate organs such as livers and lungs; and to grow new skin for victims of fire or traumatic injury. Hopes for therapy battle against concerns about the source of the stem cells, and whether human beings were destroyed to source research.

The EU efforts to ban genetically modified organisms focus on keeping the food supply free of so-called "Frankenfood," but also bring ethical challenges by inhibiting adoption of genetically modified foods in countries where hunger is endemic. Because African countries need their European trade partners, some have been reluctant challenge the EU by adopting genetically modified foods, even though such bioengineered food crops could reduce hunger by being resilient to drought and insect damage, with increased crop yields. European disapproval may preclude adoption of the enhanced crops.

Even agricultural applications of biotechnology raise potential ethical concerns. Bioengineers created plants such as marijuana or opium poppies that contain little or no psychoactive agents. One hope might be to use seeds of these plants to reduce the potency of illicit drug plants and thus reduce the illicit drug trade payoff. However, introducing these alternatives would require stealth and could be considered an act of bioterrorism. The ethical challenges trade off two goods: sovereignty versus the goal of reducing illicit drug trafficking.

Industry could use bioengineered materials, including enzymes, to bioremediate hazardous waste sites. Cleaning up long-polluted sites represents goodness. However, the process could introduce novel byproducts that have no counteragent. The "precautionary principle," often cited by European critics of GM materials, suggests that new materials must be proven safe before introduction. Of course, proving a non-threat is scientifically difficult and time consuming. What costs in life, health, and environmental security result from lengthy safety testing to a significantly higher standard? Which is the more ethical course, to allow known toxins to pollute the environment, or to introduce novel bioengineered materials into the world? All these issues point to the need to societal education and discussion.

### ***Human Capital and Education***

The United States expects biotechnology to retain its status as a leading growth industry. To stay globally competitive, America's education system must be capable of producing enough scientists, engineers, lab technicians, and biotechnology workers to meet the industry's growing demands for a highly skilled workforce. However, the Hart-Rudman Commission Report on National Security for the 21<sup>st</sup> Century<sup>66</sup> outlines the difficulties in science, technology, engineering, and mathematics (STEM) education for the United States. The report finds the quality of overall math and science instruction in United States schools is poor. In addition, there are a significantly lower number of STEM graduates that America produces annually (70,000) compared with both China (600,000) and India (350,000). In addition, the United States internally has twenty-eight accredited schools and 300 universities awarding 5,000 master and doctorate degrees in public health annually but of the students receiving degrees in biotechnology, more than three-quarters are foreign born.

The Hart-Rudman Commission uses the 1958 National Defense Education Act (NDEA) as the basis of a strategy to revamp the American education system to emphasize STEM. Before World War II, only 160,000 Americans had a college degree. However, by 1950, GI Bill initiatives brought that number to 848,000 with post-war veterans representing nearly half of the total 91,000 scientists, 67,000 doctors and other medical technicians, 450,000 engineers, and 240,000 mathematicians and accountants. In August 2007, President Bush, citing the Hart-Rudman Commission's findings, signed the America Competes Act<sup>67</sup> into law, authorizing \$51 billion for science and technology programs over fiscal years (FY) 2008-2010.

The America Competes Act inspired education outreach programs by the federal government and private organizations to grow STEM professionals. For example, DoD's Gains in the Education of Math and Science (GEMS) program supported by the Walter Reed Army Institute of Research provides summer science camps for underprivileged junior high students in mathematics, physics, chemistry, and biology. Army-sponsored University Affiliated Research Centers (UARCs) incorporate the outreach mission to increase awareness of emerging science and technologies. The Army sponsors eCybermission virtual science fairs to encourage STEM in elementary school students. In the private sector, organizations follow the lead of the Broad Institute's Education Outreach Program, in the Cambridge, Massachusetts biotechnology cluster, to provide forums, science fairs, summer internships and semester-long research programs for students and teachers. These outreach programs and others help to grow the nation's STEM workforce and ensure the US remains competitive in the global biotechnology industry.

### **The Way Ahead for Biotechnology**

For biotechnology, the future is now – to feed and fuel the world, to heal and prevent disease, and to create clean manufacturing and clean up hazardous materials in the environment. The US should pursue an active government policy to stay engaged and maintain dominance in the biotechnology field. From policies, patent law and technology transfer activities, active financing (both cost sharing and risk sharing), and STEM education investments through business and job creation, the US government should invest to support the continued healthy growth of this industry. The goal is to stimulate growth across the various sectors by leveraging biotechnology applications. The US can clearly compete in biotechnology, offsetting economic losses in the financial and automotive industries.

- Consistently provide seed money to biotechnology ventures, from basic research through applications funding, to procurement of early biotechnology products. US government funding, both from research and development funding and from defense applications, can offset losses from a decimated venture capital base resulting from the economic crisis.

- Continue to encourage the biotechnology industry to maintain American competitive and comparative advantage, across the board. Invest across the life cycle, from research and development, through early lead user adoption of the new biotechnologies, to marketing products around the globe. Streamline bureaucratic hurdles to reduce processing time for innovations to come to market.
- Reduce uncertainty by establishing policies at all levels, from local to international, to support economic development and industry expansion. Include an education campaign to increase awareness with a strategic communications component to address the technologies as well as their potential political, social, economic, ethical, and national security impacts.
- Support WTO ruling on “fair and balanced trade” internationally, so American biotechnology products can compete internationally. Work out the labeling issues. Europe makes choices about adopting US bioengineered food products and other biotechnology goods and services, and the EU’s choices affect other global allies. Countries that should benefit from biotechnology, such as poor countries in Africa, feel constrained in adopting bioengineered foods, despite the potentially increased crop yields and reduced expenditures for fertilizer and fuel. Reducing food competition reduces the potential for international conflict and makes the world safer.

## Summary

Biotechnology investments in talent and treasure can improve health care, reducing long-term care costs through better diagnostics. Biofuels can reduce American dependence on foreign fuel supplies. By stimulating the growth of the biotechnology industry, new jobs with better pay can offset job losses in other industries. Bioremediation can take back toxic land for future reuse. America would ignore this potential at its own peril. Failure to support education reform in sciences and math would diminish our competitive advantage. The loss of the innovations that biotechnology can bring, in agriculture, health care, and industrial applications, could contribute to the decrease in American dominance and national security. Continued support of biotechnology also ensures that the US remains aware of emerging opportunities and risks, becoming responsive to potential biotechnology threats and exploiting targets of opportunity brought by bio-innovation. The US leads in biotechnology, and can continue to do so.

Issues identified throughout this paper bear directly on America’s prospective achievements. In this time of economic turmoil, government’s financial and policy choices must be incisive enough to mold and pattern how we achieve biotechnological success. Only in highlighting the success achieved by, and capitalizing upon, America’s production of biotechnological applications can we stimulate our economic and intellectual potential. The coming future, with its population explosion and international risks, mandates our leadership role in good stewardship. We have the biotechnological resources and capability. As we lead the competitive biotechnology market today, so must America itself be the future of the industry.

## ENDNOTES

<sup>1</sup> United Nations Convention on Biological Diversity (1992).

<sup>2</sup> In 1953, James Watson and Francis Crick published their manuscript describing the double helix structure of the deoxyribonucleic acid (DNA) nucleic acid that contains the genes and instructions (“genetic code”) used by living organisms to build their cells. While Watson and Crick were awarded the Nobel Prize for Physiology and Medicine in 1962 for their discovery, much of the formative work was accomplished by chemist Rosalind Franklin. Her use of X-ray crystallography allowed her to discover the double helix structure of DNA. Watson and Crick built on her discovery and uncovered the base pairs joining the two strands. More information is available at [http://www.accessexcellence.org/RC/AB/BC/Rosalind\\_Franklin.php](http://www.accessexcellence.org/RC/AB/BC/Rosalind_Franklin.php). A good basic biotechnology primer is *Biotechnology Unzipped*, by Eric A. Grace, available at the National Academies Press in Washington, D.C, 2006, [www.nap.edu/catalog.php?record\\_id=5738](http://www.nap.edu/catalog.php?record_id=5738).

<sup>3</sup> Sumerians and Babylonians used fermentation to make beer. This process and its permutations spread across cultures, for food production and preservation. <http://www.accessexcellence.org/RC/AB/BC/6000BC-1700AD.php>.

<sup>4</sup> Anthropological records indicate that Central Asian people were the first to produce yogurt. More information is available at <http://www.foodtimeline.org/foodfaq2.html#yogurt>.

<sup>5</sup> Ann Murphy and Judy Perrella, “Overview and Brief History,” *Access Excellence*, [http://www.accessexcellence.org/RC/AB/BC/Overview\\_and\\_Brief\\_History.php](http://www.accessexcellence.org/RC/AB/BC/Overview_and_Brief_History.php).

<sup>6</sup> In 1976, Genentech was founded to develop therapeutic products using recombinant DNA (rDNA) technology, including insulin and human growth hormone. Genentech, “Corporate Chronology,” <http://www.gene.com/gene/about/corporate/history/timeline.html>.

<sup>7</sup> Ernst and Young, “Biotechnology Beyond Borders 2008,” Jan 15, 2009, [http://www.ey.com/Global/assets.nsf/International/Industry\\_Biotechnology\\_Beyond\\_Borders\\_2008/\\$file/Biotechnology\\_Beyond\\_Borders\\_2008.pdf](http://www.ey.com/Global/assets.nsf/International/Industry_Biotechnology_Beyond_Borders_2008/$file/Biotechnology_Beyond_Borders_2008.pdf).

<sup>8</sup> PricewaterhouseCoopers/National Venture Capital Association MoneyTree Report, 1Q 2009, April 18, 2009, <https://www.pwcmoneytree.com/MTPublic/ns/index.jsp>.

<sup>9</sup> The Human Genome Project was a 13-year, multi-national effort to identify all 25,000 genes in human DNA and to sequence the three billion base pairs that comprise DNA. Completed in 2003, the project paved the way for more research and an explosion in bioinformatics. [http://www.ornl.gov/sci/techresources/Human\\_Genome/home.shtml](http://www.ornl.gov/sci/techresources/Human_Genome/home.shtml).

<sup>10</sup> Quote taken from President Bush’s remarks when he signed the 2004 Project BioShield Act. US Department of Health and Human Services, “Project BioShield,” <http://www.hhs.gov/aspr/barda/bioshield/index.html>.

<sup>11</sup> Centers for Disease Control and Prevention. “NIOSH Respiratory Diseases Research Program,” March 12, 2009, <http://www.cdc.gov/niosh/nas/RDRP/ch6.2.htm>.

<sup>12</sup> In 2007, the US share of world production was 42.6% for corn, 32.0% for soybeans, 9.3% for wheat, and 1.5% for rice. Of global exports, the US accounted for 64.5% for corn, 39.4% for soybeans, 32.1% for wheat, and 9.7% for rice. Jim Monke, *CRS Report for Congress*, “Agroterrorism: Threats and Preparedness,” March 12, 2007. 6.

<sup>13</sup> U.S Department of Agriculture, “Agricultural Select Agents – Select Agent and Toxin List,” March 4, 2009, [http://www.aphis.usda.gov/programs/ag\\_selectagent/ag\\_bioterr\\_toxinlist.shtml](http://www.aphis.usda.gov/programs/ag_selectagent/ag_bioterr_toxinlist.shtml).

<sup>14</sup> An early example of bio-attack occurred in 1340 in modern day France during the siege of Thun L’Eveque castle. Attackers catapulted dead horses over castle walls to promote pestilence inside the walled city. Adaptation saw the rise of defensive practices such as underground water reservoirs and better urban sanitation. [http://www.pbs.org/wgbh/nova/bioterror/hist\\_nf.html](http://www.pbs.org/wgbh/nova/bioterror/hist_nf.html).

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